UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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FURMAN PEARSALL,

Plaintiff,

-against-

MEDTRONICS, INC.,

Defendant.

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MEMORANDUM AND ORDER

CV 14-3378

(Wexler, J.)

APPEARANCES:

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WEXLER, District Judge:

Plaintiff Furman Pearsall ("Pearsall" or "Plaintiff")'s complaint, based on diversity, asserts New York common law claims of strict liability manufacturing defect, negligent manufacturing and failure to warn in connection with an implantable cardiac defibrillator ("ICD") plaintiff had implanted on December 11, 2006. The ICD and the wire, or "Lead," which connected it to Plaintiff's heart, was manufactured by defendant Medtronics, Inc. ("Defendant" or "Medtronics"). On May 18, 2012, according to Plaintiff, the ICD including the Lead

malfunctioned, causing Plaintiff an unanticipated shock to his heart and requiring an emergency procedure to remove and replace the ICD. This complaint followed.

Defendant moves to dismiss pursuant to Federal Rules of Civil Procedure ("Fed.R.Civ.P."), Rule 12(b)(6), claiming that Plaintiff's claims are preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a), and the U.S. Supreme Court ruling in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). Defendant also argues that even if Plaintiff's claims are not preempted, they fail to state a claim and should be dismissed. For the reasons that follow, Defendant's motion is granted.

BACKGROUND

I. Statutory Framework

In 1976, Congress passed the MDA to the FDCA, 21 U.S.C. § 360c, *et seq.*, which created a scheme of federal oversight of medical devices.[1] The degree of oversight varies depending on the "class" of the device, with those devices in Class III garnering the most extensive oversight. Riegel, 552 U.S. at 316-317.

The regime includes a "rigorous" pre-market approval review of Class III devices, which requires the manufacturer to submit a multi-volume application that includes extensive studies and investigations of the device's safety and effectiveness, as well as a review of the proposed labeling to ensure there is nothing false or misleading in its sales and marketing. Id., at 317-319.

Once a device receives pre-market approval ("PMA"), the MDA requires the manufacturer to seek FDA permission to make any changes in design specifications,

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[1]Prior to passage of the MDA, supervision of new medical devices was largely left to individual states. Riegel, 552 U.S. at 315 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 475-476, 116 S.Ct. 2240, 135 L.Ed.2d 770 (1996)).

manufacturing processes or labeling that might effect its safety and effectiveness. Id., at 319. In addition, the scheme requires the manufacturer to inform the FDA of new clinical studies or investigations, and to report any incidents of injury or death, or malfunctioning that may cause injury or death. Id. The FDA retains power to withdraw pre-market approval, and must withdraw approval if its deems a device unsafe or ineffective. Id., at 320.

II. Plaintiff's Complaint

On December 11, 2006, Plaintiff received an ICD, Virtuous ICD VR D154VWC, attached to which was the Sprint Fidelis Lead model 6949, both manufactured by Defendant Medtronics. First Amended Complaint ("Cmplt.") ¶ 7.

In 1992, Defendant submitted a PMA to the FDA seeking approval of its Medtronic Transvene Lead System, which approval was granted in December 1993. Id. ¶ 8-9. Pursuant to the scheme described above, Medtronics submitted several supplements to the FDA seeking approval for various changes to the lead system. Id. ¶ 10. Approval for the Sprint Fidelis Lead model 6949 (the "Lead") at issue here[2] was sought through a supplement to the PMA and granted by the FDA on June 8, 2004. Id. ¶¶ 11-12.

Plaintiff's complaint states that pursuant to this approval, Defendant was required to, *inter alia,* submit PMA supplements if it sought to make any changes to the device, report any studies or data reports concerning the device of which it was aware or should have been aware, and report any adverse reactions to or malfunctions of the device, including those not addressed

[2]To the extent there is a distinction drawn in Defendant's papers regarding the particular lead at issue, Plaintiff asserts the references in its complaint to a lead are intended to refer to the Sprint Fidelis Lead model 6949. See Plaintiff's Memorandum in Opposition ("Pl. Mem."), at 3 n.1.

in its labeling. Id. ¶¶ 13-16.

According to Plaintiff, Defendant made several significant changes to the Lead that related to its safety and effectiveness without submitting a PMA supplement to the FDA. Id. ¶¶ 17-23. Plaintiff also alleges that various problems related to the manufacture of the Lead were not reported as required. Id. ¶¶ 24-32. Specifically, Plaintiff alleges that the Leads were manufactured using a process known as "spot welding" to joined two metal surfaces, that caused damage in the Leads and the fine wires in the cables. Id. ¶ 25-26. Further, Plaintiff alleges that a subsequent investigation of Defendant's plant in Villalba, Puerto Rico revealed that the manufacturing process was one possible cause of the fracture failures, and that the facility had a history of manufacturing violations. Id. ¶¶ 27-32. Plaintiff asserts that Defendants' "manufacture, packing, storage or installation of the Leads were not in conformity with applicable FDA rules and regulations." Id. ¶ 32.

Plaintiff also claims that Defendant failed to conform with the Current Good Manufacturing Practices ("CGMP") required by the FDA, which establish basic minimum requirements applicable to manufacturers of finished medical devices. Id. ¶ 33. Plaintiff alleges that Defendant's failure to adhere to the CGMPs included, *inter alia,* failure to adequately test and take corrective actions of deficiencies to ensure the Leads could withstand the required forces after implantation. Id. ¶¶ 34-40.

Finally, Plaintiff asserts that in violation of the conditions of approval, Defendant failed to report adverse events concerning the Leads, or in the time period required. Id. ¶¶ 41-42. Plaintiff claims a database indicates that many of Defendant's adverse event reports were filed between 85 and 136 days after the event, and that Defendant filed "hundreds" of adverse event

reports on September 10, 2007. Id. ¶¶ 43-48.

On October 15, 2007, Defendant announced a recall of the Sprint Fidelis Lead model 6949, and physicians were advised to stop using the Leads and return all remaining Leads to Defendant. Id. ¶ 49. Thereafter, the FDA issued a Class I Recall[3] of the Lead. Id. ¶ 50. Despite this risk, Defendant advised that those that already had an implanted Lead (such as Plaintiff) should not routinely seek removal, since the health risks were minimal. Id.

Plaintiff alleges that on May 18, 2012 his ICD and Lead malfunctioned, causing an "unanticipated shock to the heart," necessitating an emergency procedure to remove the ICD and Lead. Id. ¶¶ 51-53.

DISCUSSION

I. Standards on Motion to Dismiss

The standards on a motion to dismiss are well-settled. In considering a motion to dismiss made pursuant to Rule 12(b)(6), the court must accept the factual allegations in the complaints as true and draw all reasonable inferences in favor of the plaintiff. Lundy v. Catholic Health System of Long Island Inc., 711 F.3d 106, 113 (2d Cir. 2013) (citations omitted); Martine's Service Center, Inc. v. Town of Wallkill, 2014 WL 321943, *1 (2d Cir. 2014) (citations omitted); Ruston v. Town Bd. for Town of Skaneateles, 610 F.3d 55, 58-59 (2d Cir. 2010). In Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), the Supreme Court rejected the standard set forth in Conley v. Gibson, 355 U.S. 41 (1957) that a complaint should not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which

[3]A Class I Recall applies when there is a "reasonable probability" that use of the device will cause "serious injury or death." Id.

would entitle him to relief." Id. at 45-46. The Supreme Court discarded the "no set of facts" language in favor of the requirement that plaintiff plead enough facts "to state a claim for relief that is plausible on its face." Twombly, 550 U.S. at 570; see also Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). The "short and plain" pleading standard of Rule 8 of the Fed.R.Civ.P. does not require "'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Iqbal, 556 U.S. at 678, quoting Twombley, 550 U.S. at 555 (other citations omitted). Although heightened factual pleading is not the new standard, Twombley holds that a "formulaic recitation of cause of action's elements will not do. Factual allegations must be enough to raise a right to relief above the speculative level." Twombley, 550 U.S. at 555.

"Determining whether a complaint states a plausible claim for relief" is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Iqbal, 556 U.S. at 679. Reciting bare legal conclusions is insufficient, and "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Iqbal, 556 U.S. at 679. A pleading that does nothing more than recite bare legal conclusions is insufficient to "unlock the doors of discovery." Iqbal, 556 U.S. at 678-679.

II. Preemption of State Law Claims

A. The Legal Principles

As noted above, the ICD and Lead at issue here, the Sprint Fidelis Lead model 6949, was approved by the FDA through the PMA process governed by the MDA. To ensure consistency after the rigorous review and approval process, the MDA includes a preemption clause which

states that:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

This ensures that no state's requirements can interfere with the rigorous and intensive review process utilized by the FDA to ensure the health and safety of Class III medical devices. The FDA retains exclusive authority to enforce or restrain violations of the FDA requirements. See 21 U.S.C. § 337(a); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (FDCA leaves "no doubt" that the FDA, not private litigants, is authorized to file suit regarding noncompliance with medical device provisions).

In Reigel v. Medtronic, Inc., the U.S. Supreme Court ruled that the MDA preempts those state requirements that are "different from, or in addition to" any federal requirement that is applied to the device. 552 U.S. 312, 330 (2008). Riegel brought state law claims of strict products liability, breach of implied warranty, and negligent design and manufacture claims concerning the catheter used in his angioplasty proceeding. The question at issue was whether the preemption clause of the MDA barred those "common-law claims challenging the safety and effectiveness of a medical device given pre-market approval by the [FDA]." Id., at 315.[4]

After describing the extensive and rigorous approval process required by the MDA and reviewing the language in the preemption clause, the Court adopted a two-step approach to

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[4]The district court in the Northern District of New York dismissed the claims and the Second Circuit affirmed. Riegel v. Medtronic, Inc., No. 99-CV-0649, 2003 WL 25556778 (N.D.N.Y. Dec. 2, 2003), aff'd, 451 F.3d 104 (2d Cir. 2005).

determine if the claims were parallel or preempted: first, to determine whether there are federal requirements applicable to the device in question; and, second, to determine whether the common law claims are based on state requirements that are "different from, or in addition to" those requirements and relate to safety and effectiveness. Id., at 321-322.

The Court found that the MDA pre-approval process did impose "requirements," stating "[i]t *is* federal safety review," that provides a "reasonable assurance of safety and effectiveness." Id., at 322-323 (italics in original). Turning to the second step, it found that a state's "'requirements' include its common-law duties," id., at 324, and held that such requirements are preempted if "different from, or in addition to" the federal requirements. Id., at 330.

The Court found the common law claims were preempted, affirming the Second Circuit's ruling since the claims "'would, if successful, impose state requirements that differed from, or added to' the device-specific federal requirements." Id., at 321. Yet, the Court noted that certain "parallel" state-based claims could proceed if based on a violation of a state law that is the same as the federal requirements, since "§ 360 does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." See Riegel, 552 U.S. at 330 (§ 360k does not preempt a claim based on state duties that "parallel" rather than add to federal requirements).[5]

Subsequent courts noted the "narrow gap" of permissible state claims following Riegel. A plaintiff's claim can fit through the "narrow gap" and avoid preemption if it is based on "conduct that *violates* the FDCA..., but not "*because* the conduct violates the FDCA." In re

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[5]The Court noted the Riegel plaintiffs had not previously argued that their claims were parallel, and therefore declined to address that issue. Riegel, 552 U.S. at 330.

Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (italics in original) (quoting Riley v. Cordis Corp., 625 F.Supp.2d 769, 777 (D.Minn. 2009)); see also Ilazarra v. Medtronic, Inc., 677 F.Supp.2d 582, 585-586 (E.D.N.Y. 2009) (Riegel "left open a narrow class of state court actions" for damages caused by federally regulated medical devices); Leroy v. Medtronic, Inc., No. 14-CV-284, 2015 WL 4600880, at *4 (N.D. Fl. July 29, 2015). In other words, a claim is permissible if it is based on conduct that violates the federal requirements and state law for the same conduct.

B. Is a Claim Parallel?

Following the recall of the Sprint Fidelis Lead, on February 21, 2008, various lawsuits filed throughout the country against Medtronics were consolidated in a multi-district litigation ("MDL") concerning the Sprint Fidelis Leads, including the model 6949 at issue here. See In re Medtronic, Inc., Sprint Fidelis Leads Products Liability, 592 F.Supp.3d 1147, 1153-1154, n. 8 (D.Minn. 2009) ("Sprint Fidelis Leads Litig. I"). The master complaint contained twenty-one claims based on common law and state law theories. The court granted defendant's motion to dismiss with prejudice, finding the claims were not "parallel" to the federal requirements and therefore preempted. The Eighth Circuit Court of Appeals affirmed. In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig., 623 F.3d 1200 (8th Cir. 2010) ("Sprint Fidelis Leads Litig. II").

In dismissing, the district court overseeing the MDL addressed the category of claims, organized as manufacturing defect claims, failure to warn claims, design defect claims, and negligence claims. Plaintiff's manufacturing defect claims were based on the assertion that the manufacturing techniques used were defective since they failed to adhere to the CGMPs, and that

the testing and quality assurance protocols were also defective. Id., 592 F.Supp.3d at 1157. The court found these claims were not "parallel" since the CGMPs provide only "general objectives" and don't "prescribe in detail how a manufacturer must produce a specific device." Id., at 1157. Since the CGMPs didn't include a specific welding requirement, to hold Medtronic liable for a "welding 'defect'" would impose a requirement "different from, or in addition to" those required by federal law, id., at 1158, and therefore the claims were preempted.[6]

The MDL district court also found plaintiffs' failure to warn claims were preempted. It ruled that the complaint failed to allege a specific rule or regulation under state law that required a warning. Id., at 1160. The court also ruled that to the extent plaintiff's failure to warn claim was based on defendant's failure to report adverse events to the FDA as required by the PMA process, that claim failed since there is no private cause of action for violations of the FDCA. Id., at 1160-1161.[7]

Finally, that court ruled that plaintiffs' design defect claims were also preempted. The claims asserted that the defendant should have sold its "new and improved" version in favor of

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[6]The court also found that the claims failed to state a cause of action because "merely alleging" that the design technique violated the CGMPs was insufficient "without some factual detail about *why* that violates federal standards." Id., at 1158 (citing Twombley, 127 S.Ct. at 1964-65).

[7]The court observed that while Riegel left a "narrow gap" for parallel claims, that gap was narrower still as a result of the FDA's exclusive right of enforcement under 21 U.S.C. § 337(a). Id., at 1161, n. 17 (discussing the interplay of Riegel and Buckman, and opining that permissible claims would include those claiming a specific device was not manufactured in accordance with the PMA specifications, or pursuant to a state-legislated remedy for violation of the FDCA). See also Sprint Fidelis Leads Litig. II, 623 F.3d at 1204 (to avoid preemption, the state-law claim must be "for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman)") (citations omitted).

its older "defective" version. The court found the claims were preempted since plaintiff failed to allege any federal requirement that mandated that defendant sell a "new and improved" model, even if one was available and approved. Id., at 1162. Permitting a state claim that mandates the defendant manufacturer to take steps to improve a device would be akin to requiring "different or additional" than those required by federal law, and is expressly preempted. Id., at 1162.[8]

Plaintiff argues that other circuits have ruled that the claims here do not rely on duties that are "different for, or in addition to" those required under state law and are permissible. For example, in Hughes v. Boston Scientific Corp., 631 F.3d 762, 768 (5th Cir. 2011), the Fifth Circuit found that plaintiff's claim for failure to warn for not complying with the FDA reporting requirements (with respect to a different device) was not preempted because there was a "state duty to provide reasonable and adequate information about a device's risks" that paralleled the FDA requirements.[9] Id., 770-771. Thus, since the claim was based on duties that were parallel to the federal requirements and did not impose duties "different from or in addition" to, it was permissible.[10]

Plaintiff also argues the decision of the Seventh Circuit in Stengel v. Medtronic Inc., 704

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[8]Other courts have ruled that common law claims stemming from the Sprint Fidelis Lead model 6949 are preempted. See e.g. Leroy v. Medtronic, Inc., 2015 WL 4600880, at *8 (N.D. Fl. July 29, 2015) (plaintiff's design defect claim "is plainly preempted," citing Sprint Fidelis Leads Litig. I and Sprint Fidelis Leads Litig. II).

[9]The court noted that Mississippi law had been construed to create a manufacturer's duty to provide reasonable warning of risks. Hughes, 631 F.3d at 769.

[10]The court affirmed dismissal of the failure to warn claims that questioned FDA's approval of the devices' labels, warnings and instructions, finding they were preempted. Hughes, 631 F.3d at 769.

F.3d 1224 (7th Cir. 2013) governs. There, the Court found that plaintiff's negligence claim was not preempted, acknowleding that "Arizona state law has long been concerned with the protection of consumers from harm caused by manufacturer's unreasonable behavior" and since the "state-law duty parallels a federal-law duty," the claim was not preempted. Id., 704 F.3d at 1233.

B. Disposition of the Motion

As stated in Riegel, the two-step inquiry to determine if a claim is parallel asks 1) whether there are federal requirements applicable to the device in question; and, 2) whether the common law claims are based on state requirements that are "different from, or in addition to" those requirements and relate to safety and effectiveness. Id., at 321-322.

It has been repeatedly held that the PMA process imposes the federal requirements required by the first prong. Riegel, at 322-323; Hughes v. Boston Scientific Corp., 631 F.3d 762, 768 (5th Cir. 2011); Wolicki–Gables v. Arrow International, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) (holding that medical device's pre-market approval "imposes specific requirements on it that are sufficient to preempt a state law claim"); Bass v. Stryker Corp., 669 F.3d 501, 507 (5th Cir. 2012) (applying Riegel and stating that "[d]evices that are approved through PMA procedures automatically satisfy the 'federal requirements' prong" of the preemption inquiry (citing Riegel, 552 U.S. at 322)) Leroy v. Medtronic, Inc., 2015 WL 4600880, *3 (N.D. Fl. July 29, 2015) (the first condition is satisfied when the FDA has approved a Class III device after the PMA process); Rosen v. St. Jude Medical, Inc., 41 F.Supp.3d 170, 177 (N.D.N.Y. 2014).

This Court thus turns its attention to whether the second prong is satisfied -- whether claims in this case are based on state requirements that are "different from, or in addition to" the

federal requirements imposed by the PMA process or whether they are permissible "parallel" claims.

1. Manufacturing Defect Claims

Plaintiff's first two claims are for "strict liability manufacturing defect" and "negligent manufacturing." Defendant argues these manufacturing defect claims are not "parallel" since there are no state requirements that mimic the federal requirements at issue. Plaintiff's claims are based on allegations that the Defendant failed to follow the "good practices" of the CGMP; that manufacturing defects resulted because Defendant failed to submit supplemental PMAs as it changed the Lead, including the use of "spot welding"; and, that defects resulted from the manufacturing violations that occurred at Defendant's facility in Villalba, Puerto Rico. Defendant argues that even if such violations occurred, since there are no identical state law requirements, there is no parallel claim and the claims are preempted.

a. Violation of the CGMPs

Plaintiff's complaint alleges that Defendant failed to adhere to the "minimum standards" created by the CGMPs, primarily by failing to adequately test the Sprint Fidelis Leads and/or its components. Cmplt., ¶¶ 33, 38. Defendant argues that alleged violations of the CGMPs cannot substantiate a permissible manufacturing defect claim because the CGMPs are merely flexible guides to the manufacturer of medical devices, not mandates, and to hold Defendant liable for compliance to flexible guidelines is the equivalent to imposing "different, or additional" demands that are impermissible and preempted.

Various courts have acknowledged that the CGMPs do not establish firm mandates. This Court in Ilarraza v. Medtronic, Inc., 677 F.Supp.2d 582 (E.D.N.Y. 2009) found that the CGMPs

are a general statement of standards that are "intentionally vague and open-ended," susceptible to an individual manufacturer's interpretation, and therefore necessarily create potentially varying standards that would be "different from, or in addition to" those required by the federal scheme, and therefore preempted. Ilarraza, 677 F.Supp.2d at 588 (citing Horowitz v. Stryker Corp., 613 F.Supp.2d 271, 278-79 (E.D.N.Y. 2009) and Spring Fidelis Leads Litig. I, 592 F.Supp.2d at 1157). The Eighth Circuit similarly held when it affirmed dismissal of the claims in the Sprint Fidelis Leads MDL. See Sprint Fidelis Leads Litig. II, 623 F.3d 1200, 1206 (8th Cir. 2010) (plaintiff's claim for manufacturing defect is preempted where plaintiff claimed general failure to comply with CGMPs but failed to allege a violation of a specific federal requirement).

In affirming the dismissal by the district court overseeing the Sprint Fidelis Lead MDL, the Eighth Circuit noted that the district court concluded that claims based on failure to abide by the CGMPs – which are an "'an umbrella quality system' providing 'general objectives' for all device manufacturers" – were preempted. Sprint Fidelis Leads Litig. II, 623 F.3d at 1206 (citations omitted). In affirming, the Eighth Circuit found that the claims as pleaded and argued, "were a frontal assault on the FDA's decision to approve a PMA supplement" and were preempted. The Court recognized that challenge of a plaintiff to plead such a claim prior to discovery, but found that the plaintiff failed to adequately plead that Medtronic violated a federal requirement specific to the FDA's PMA approval, and affirmed the district court. Id., at 1207.

This Court is persuaded by its earlier reasoning in Ilarraza and the Eighth Circuit in Sprint Fidelis Leads Litig. II. The CGMPs are guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with the guidelines fails to plead violation of a federal requirement. Id. To permit a claim that mandates compliance with such "vague" standards

effectively imposes "different, or additional" requirements, and is preempted by§ 306. Ilarraza, 677 F.Supp.2d at 588; Sprint Fidelis Leads Litig.I, 592 F.Supp.2d at 1157-58 (since CGMPs are "simply too generic, standing alone, to serve as the basis for Plaintiff's manufacturing-defect claim[,]" to hold Medtronic liable for conduct, in "the absence of a specific requirement in the CGMPs...would impose requirements 'different from, or in addition to' those under federal law") (citations omitted). See also Burkett v. Smith & Nephew Gmbh, 2014 WL 1315315, at *5 (E.D.N.Y. 2014) (manufacturing claim preempted where based on violation of "generally applicable CGMPs" rather than federal requirements)

b. Failure to Submit Supplements to the PMA

Plaintiff's manufacturing defect claims is also based on Defendant' alleged failure to submit supplements to the PMA concerning significant changes it made the Lead. Plaintiff claims that changes were only reported in annual reports, in violation of the conditions of approval. Cmplt., ¶¶ 17-23. Even assuming these conditions constitute "requirements" under federal law, Plaintiff fails to show that there is a similar parallel requirement under state law that a manufacturer provide supplements to the FDA.

Plaintiff argues generally that New York law "imposes the same obligations." See Plaintiff's Memorandum ("Pl. Mem."), at 1-2, 8. He argues that the reasoning of Mitaro v. Medtronic, Inc., 23 Misc.3d 1122(A), 886 N.Y.S 71, 2009 WL 1272398 (Sup.Ct. 2009), aff'd 73 A.D.3d 1142 (2d Dept. 2010) applies. In that case, the court addressed a motion to dismiss thirteen claims regarding the Sprint Fidelis Lead model 6949. While Plaintiff correctly notes that the court there ruled that the strict liability claim based on a manufacturing defect was properly

pled and was not dismissed,[11] it found that plaintiffs' other claims, including those for failure to warn, for strict liability for defective design, for negligent design, testing, manufacturing, and marketing, for breach of implied warranty,[12] were preempted by the MDA and Riegel, finding that the claims which "challenged the FDA's findings...necessarily imposes requirements that are different from, or in addition to, federal regulations," and are preempted. Mitaro, 2009 WL 1272398, at *3. Indeed, in affirming, the Second Department found that the claims for strict liability based on failure to warn and defective design, negligence, negligence per se, and breach of implied warranty were preempted "because the claims alleged by the plaintiffs under state law impose requirements with respect to the medical device at issue here that are "different from, or in addition to [the federal] requirement," and because they relate to either the "safety or effectiveness" of the medical device under the MDA." Mitaro v. Medtronic, Inc., 73 A.D.3d 1142 (2d Dept. 2010) (citing 21 USC §§ 360k(a)(1),(2); Reigel v. Medtronic, Inc., 552 U.S. 312, 324–325, 128 S.Ct. 999, 169 L.Ed.2d 892; and Sprint Fidelis Leads Litig. I, 592 F.Supp.2d 1147, 1158–1164).

This Court finds that Plaintiff's manufacturing defect claim based on Defendant's alleged failure to submit supplemental PMAs to the FDA is preempted. Plaintiff fails to point to any state law that parallels the federal requirement that such supplements be submitted, or provides a a state law remedy for the failure. "The parallel claim, however, must arise from an actual state-law requirement; it cannot exist 'solely by virtue of the FDCA ... requirements.'" Leroy v.

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[11]The court found, without explanation, that the strict liability manufacturing defect claim was parallel to a claim based on violations of the federal requirements, and was sufficiently pled to give defendant requisite notice. Id., 2009 WL 1272398, at * 3.

[12]The claim for breach of express warranty was not dismissed.

Medtronic, Inc., 2015 WL 4600880, at *3 (citing Buckman, 531 U.S. at 352-53); In re Medtronic Sprint Fidelis Lead Products Liability State Court Litigation, 2009 WL 3417867, at *16 (Minn.Dist.Ct. Oct. 20, 2009) ("Sprint Fidelis Leads State Litig.") (in a state case concerning same leads as the MDL, any claim for failure to provide reports to the FDA is not a parallel claim). To hold a defendant to a standard that does not track the federal requirement creates a duty that is "different from, or in addition to" the federal requirements and is preempted. Riegel, 552 U.S. at 330 (citations omitted); Ilzarra, 677 F.Supp.2d at 588 (citations omitted). Instead, the state remedy must be based on a state duty that parallels, or is "generally equivalent" to the federal requirements. Wolicki-Gables, 634 F.3d at 1300 (citations omitted).

Furthermore, to the extent Plaintiff's claim seeks to enforce an FDA requirement for PMA supplements, that right of enforcement rests solely with the FDA and the claim is impliedly preempted. See 21 U.S.C. § 337(a); Buckman, 531 U.S. at 352-53; Sprint Fidelis Leads State Litig., 2009 WL 3417867, at *19 (claims based on failure to provide supplements do not seek to enforce a common-law duty, but the FDA requirements, which is left solely to the FDA); Leroy, 2015 WL 4600880, at *3 ("actions seeking to enforce an exclusively federal requirement not grounded in traditional state tort law are impliedly preempted by section 337(a)"). Since there is no state duty that is "generally equivalent" to one requiring a manufacturer to submit supplements following an initial approval, the claim is not parallel and is preempted.

c. Problems with at Villalba Facility

The third theory to Plaintiff's manufacturing defect claims is based on alleged manufacturing violations of the FDA standards at Defendant's facility at Villalba, Puerto Rico and through the use of "spot welding" to fuse the Leads. Cmplt., ¶¶ 25-32. This same claim, that

the welding technique made the Leads defective, was addressed by the state court overseeing the state cases "companioned" to the Sprint Fidelis Leads MDL. See Sprint Fidelis Leads State Litig., 2009 WL 3417867 (Minn.Dist.Ct. 2009). In addressing defendant's motion to dismiss, the court found the manufacturing- and design-defect claims, based on strict liability and negligence, were preempted by § 360k. The court found that the FDA specifically approved the design and proposed manufacturing processes when it approved the Leads, and therefore, any claim challenging that is effectively asking a jury to substitute its own judgment for that of the FDA, which is empowered with sole authority to determine the safety of the device, considering interests and for reasons that go beyond this individual plaintiff. Id., 2009 WL 3417867, at *13-14 (citing Riegel, 128 S.Ct. at 1007; Sprint Fidelis Leads Litig. II, 2009 WL 361313, at *2 (dismissing identical claims in MDL as preempted)).

This Court is persuaded by this reasoning. First, again Plaintiff fails to point to a "generally equivalent" state duty that imposes similar manufacturing standards (or welding methods) as those required by the FDA. Furthermore, permitting such a claim is akin to asking a jury to sit in judgment of the FDA's approval and review process -- a result the MDA's preemption clause and § 337(a) were intended to prevent. Plaintiff's claims for a manufacturing defects based on the alleged violations at the Villalba facility and/or the use of spot welding are preempted.

* * *

Like other courts who have examined claims concerning the Sprint Fidelis Lead, this Court finds that Plaintiff's manufacturing defect claims are preempted. See Sprint Fidelis Leads Litig. I, 592 F.Supp.2d at 1156-1163 (plaintiffs' claims for manufacturing defect, failure to warn,

and design defects are preempted; Sprint Fidelis Leads Litig. II, 623 F.3d at 1205-1207; Leroy v. Medtronic, Inc., 2015 WL 4600880, at *8 (plaintiff's claim, which sounds is design defect, "is plainly preempted," citing Sprint Fidelis Leads Litig. I and Sprint Fidelis Leads Litig. II); Sprint Fidelis Leads State Litig., 2009 WL 3417867, at *11, 13-14 (all claims alleging defects in the design, manufacturing, testing, labeling and warnings are preempted, since "[a] state law claim that would permit a jury to substitute its judgment for that of the FDA and conclude that the health benefits of the Leads were outweighed by their risks would necessarily impose additional or contrary requirements upon an FDA-approved medical device, and is thus preempted under Riegel") (other citations omitted). But see Mitaro v. Medtronic, Inc., 23 Misc.3d 1122(A), 886 N.Y.S 71, 2009 WL 1272398, at *3-4 (without discussion on whether the claim is parallel, plaintiff's manufacturing defect claim is not preempted where adequately pled; design defect claim is not parallel and preempted).

2. Failure to Warn Claim

Plaintiff's failure to warn claim stems from Defendant's alleged failure to report post-approval adverse events and warnings and instructions regarding safety hazards and/or potential defects with the Leads to the FDA, and that had these warnings been provided, they would have reached Plaintiff's treating medical professionals in time to prevent Plaintiff's injuries. Cmplt., ¶¶ 65-68.

Defendant argues that the Eighth Circuit has already ruled that a state law failure to warn claim based on failure to provide warnings where state law would impose a "different" requirement than that required by the FDA are preempted; and that a failure to warn claim based on failure to report post-approval adverse events is an attempt by private parties to enforce the

MDA, which is precluded by the exclusive enforcement authority granted to the FDA by § 337(a). Sprint Fidelis Leads Litig. II, 623 F.3d at 1205-1207.

Plaintiff argues that the Court should instead be controlled by Hughes v. Boston Scientific Corp., 631 F.3d 762 (5th Cir. 2011) and Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013). In Hughes, the Fifth Circuit held that the failure to warn claim was not preempted since the Mississippi code created a duty to warn and accurately report serious injuries and malfunctions of the device in the same manner as required by the federal requirements. Hughes, 631 F.3d at 770-771. Thus, the state law was parallel to the federal requirements and not preempted. Id., 631 F.3d at 771. Similarly, in Stengel, the Ninth Circuit found that the Arizona state law tracked the federal requirements, mandating manufacturers to produce "appropriate warning instructions," which is a "continuing [duty] applying to dangers the manufacturer discovers after sale," and includes a duty to warn third-parties, such as the FDA. Stengel, 704 F.3d at 1233 (citations and internal quotations omitted). In so finding, the Ninth Circuit reiterated that claims that are not based on parallel state law duties are preempted. Id., at 1233. Thus, as in Hughes, the state law duties at issue in Stengel paralleled the duties created by the federal requirements.

Finally, Plaintiff also claims that Rosen v. St. Jude Medical, Inc., 41 F.Supp.3d 170 (N.D.N.Y. 2014) is instructive. There the district court stated that New York law requires a manufacturer to warn, not the patient but medical providers, and that the duty is a continuing one. Id., at 183-184. The Rosen court found that this state law duty to report to the medical profession was parallel to the federal duty to report adverse events and provide ongoing warnings to the FDA. Id., at 184. The plaintiff claimed violations of the federal duty to report to the FDA led to

a failure to inform the medical community as required by state law. Id., at 185. The court concluded that since New York law imposed a similar duty, the failure to warn claim was parallel and therefore preempted. Id., at 185.

The Court finds these cases distinguishable. Hughes and Stengel both turned on the courts' finding that the Mississippi and Arizona respective state duties to warn tracked the federal requirements. The Rosen court also concluded that the New York state duty to warn imposed a duty similar to the one imposed by the federal requirements, finding that the state duty to warn medical professionals was parallel to the federal duty to warn the FDA. Rosen, 41 F.Supp.3d at 185. This Court disagrees that the New York state duty to warn is parallel to the federal requirements.

Under New York law, a drug manufacturer's duty is not to warn the patient, but "to warn the medical profession of dangers inherent in its biological drugs which, in the exercise of reasonable care, it knew or should have known to exist.'" Baker v. St. Agnes Hospital, 421 N.Y.S.2d 81, 85, 70 A.D.2d 400, 405 (2d Dept. 1979) (quoting Tinnerholm v. Parke Davis & Co., 285 F.Supp. 432, 451 (S.D.N.Y. 1968)). The continuing obligation is to 1) stay current with knowledge of its products, and 2) to take reasonable steps to share that with the medical profession. Baker, 421 N.Y.S.2d at 85 (citations omitted). See also Mulhall v. Hannafin, 841 N.Y.S.2d 282, 285, 45 A.D.3d 55, 58 (1st Dept. 2007) (under New York law, the manufacturer of a medical device has a duty to warn the medical community, not the patient of the product's risk).

The federal requirements require that adverse events and other reports be made to the FDA. While New York law may require manufacturers to warn the medical profession, that is not the same as a duty to report to the FDA. Thus, since the state law duty imposes obligations

that are "different from, or in addition to" the federal requirements, the Court finds that Plaintiff's failure to warn claim is preempted. Riegel, 552 U.S. at 321-322. See Bertini v. Smith & Nephew, Inc., 8 F.Supp.3d 236, 256 (E.D.N.Y. 2014) (plaintiff's failure to warn claim is preempted by the MDA where plaintiff is unable to show state and federal requirements are parallel); Horowitz v. Stryker Corp., 613 F.Supp.2d 271, (E.D.N.Y. 2009) (plaintiff's failure to warn claim concerning a medical device that received PMA approval is preempted by MDA). See also Leroy v. Medtronic, Inc., 2015 WL 4600880, at *3 (there must be an actual state-law duty, beyond the federal duty, to have a parallel claim); Wolicki-Gables, 634 F.3d at 1300 (state remedy must be based on a state duty that is "generally equivalent" to the federal requirements); Sprint Fidelis Leads Litig. I, 592 F.Supp.2d at 1156-1163 (failure to warn claim is preempted because plaintiff fails to identify equivalent state law requirement and there is no private right of action to enforce FDA requirements).

The Court also finds that since Plaintiff's failure to warn claim is predicated on Defendant's alleged failure to provide the required reports to the FDA, authority to enforce that claim rests with the FDA. See 21 U.S.C. § 337(a); Sprint Fidelis Leads Litig. I, 592 F.Supp.2d at 1160-1161.

Having concluded that all of Plaintiff's claims are preempted, the Court finds it unnecessary to address Defendant's additional argument that Plaintiff's claims fail to state a claim and should be dismissed.

CONCLUSION

For the reasons stated above, Defendant's motion to dismiss is granted in its entirety, and Plaintiff's complaint is hereby dismissed with prejudice.[13] The Clerk of the Court is directed to close the case.

SO ORDERED.

s/ Leonard D. Wexler

LEONARD D. WEXLER
UNITED STATES DISTRICT JUDGE

Dated: Central Islip, New York
December 7, 2015

[13]The Court denies Plaintiff's request that this motion be granted without prejudice.